EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF
WEST VIRGINIA AT CHARLESTON

- - -

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:Master File No. :2:12-MD-0237 : :MDL No. 2327
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	:JOSEPH R. GOODWIN :U.S. DISTRICT JUDGE

Mullins, et al. V. Ethicon, Inc., et al.
2:12-cv-02952
Sprout, et al. V. Ethicon, Inc., et al.
2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.
2:12-cv-09765
Daniel, et al. V. Ethicon, Inc., et al.
2:13-cv-02565
Dillon, et al. V. Ethicon, Inc., et al.
2:13-cv-02919
Webb, et al. V. Ethicon, Inc., et al.
2:13-cv-04517
Martinez v. Ethicon, Inc., et al.
2:13-cv-04730
McIntyre, et al. V. Ethicon, Inc., et al.
2:13-cv-07283
Oxley v. Ethicon, Inc., et al. 2:13-cv-10150
Atkins, et al. V. Ethicon, Inc., et al.
2:13-cv-11022
Garcia v. Ethicon, Inc., et al. 2:13-cv-14355
Lowe v. Ethicon, Inc., et al. 2:13-cv-14718
Dameron, et al. V. Ethicon, Inc., et al.
2:13-cv-14799

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CAPTION CONTINUED:

Vanbuskirk, et al. V. Ethicon, Inc., et al.
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Mullens, et al. V. Ethicon, Inc., et al.
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Shears, et al. V. Ethicon, Inc., et al.
2:13-cv-17012
Javins, et al. V. Ethicon, Inc., et al.
2:13-cv-18479
Barr, et al. V. Ethicon, Inc., et al.
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Stevens v. Ethicon, Inc., et al.
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Matney, et al. V. Ethicon, Inc., et al.
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Jones, et al. V. Ethicon, Inc., et al.
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2:14-cv-10640
Gillum, et al. V. Ethicon, Inc., et al.
2:14-cv-12756
Whisner, et al. V. Ethicon, Inc., et al.
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Schepleng v. Ethicon, Inc., et al.
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Tyler, et al. V. Ethicon, Inc., et al.
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Kelly, et al. V. Ethicon, Inc., et al.
2:14-cv-22079
Lundell v. Ethicon, Inc., et al.
2:14-cv-24911
Cheshire, et al. V. Ethicon, Inc., et al.
2:14-cv-24

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it then or -- was that your question?
Q. Yes. When you would place the Ethicon branded, you know, PROLENE® polypropylene sling for stress urinary incontinence, where at the mid urethra would you place it?
MS. FITZPATRICK: Objection.
THE WITNESS: As I said, I would place it in the mid urethra.
BY MR. SNELL:
Q. What data did you rely upon for the mid urethral placement of the Ethicon branded sling at the mid urethra?
MS. FITZPATRICK: Objection. Are you talking about the mesh or are you talking about a particular sling?
MR. SNELL: I'm talking about the slings he's testified he placed.
MS. FITZPATRICK: I just want to make sure we're clear here.
THE WITNESS: I haven't

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thought about this in a very long time, and it occurred to me that I misspoke just now.
In the few that I did, I did not place them at the mid urethra, I placed them at the bladder neck.
BY MR. SNELL:
Q. So in the few PROLENE® polypropylene slings that you placed at the bladder neck, why would you have chose that location?
MS. FITZPATRICK: Objection to form. I just want to make sure we're on the same page.
There's the slings that Ethicon makes, the TVT --
MR. SNELL: I know. You're making a speaking objection. What's your point?
MS. FITZPATRICK: I don't understand what your question is.
Are you talking about those or are you talking about where he has testified that he has hand cut

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some of the PROLENE® mesh before to place it? I'm not sure what you're talking about.
BY MR. SNELL:
Q. Have you ever placed a TVT?
A. No.
Q. Every Ethicon branded PROLENE® polypropylene sling you placed were slings that you hand cut, correct?
A. Correct.
Q. And you hand cut them at a 2 centimeter wide strip, correct?
A. Correct.
Q. And those are the slings -- synthetic slings, that you've done, correct?
A. That's correct.
Q. Okay. And you testified that you would place those -- strike that.
You changed your testimony, and you testified that you placed those at the bladder neck, correct?
MS. FITZPATRICK: Objection.

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THE WITNESS: Correct.
BY MR. SNELL:
Q. Why would you place them at the bladder neck?
A. Because I believe there's a learning curve for everything that you do. And even that little change from the mid urethra to the bladder neck, I didn't think it was necessary to subject the patient to a new learning curve for that part of the operation.
Because the autologous slings had been so successful, that I thought it best to -- to mimic exactly that same operation but using the synthetic sling because of other concerns.
Q. When you made the decision to place the PROLENE® polypropylene slings at the bladder neck, were you relying on any data in the medical literature for that determination?
A. Yeah, I was relying on my own published experience, published

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(Whereupon, Exhibit Blaivas-4, Article, Safety Considerations for Synthetic Sling Surgery, was marked for identification.)

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BY MR. SNELL:

Q. So, Doctor, you're at Page 5?

A. I am.

Q. And in your review paper, you wrote -- and I'm on Page 5 at the top paragraph.

MS. FITZPATRICK: When you say Page 5, I start at 481.

THE WITNESS: That's what I'm saying, these are actually numbered 1, 2, 3, 4, 5 and this, for whatever reason, is completely different page numbering.

I'm the same as you.

MS. FITZPATRICK: My 485 is your Page 5. Good enough.

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Thanks.

BY MR. SNELL:

Q. It says, We estimate that bowel perforation and serious infections have a combined incidence of about 0.1 percent.

Correct?

A. Where are you now?

Q. Page 5, top right column.

A. Yes.

Q. And then there are citations to papers numbered 117 to 134, correct?

A. Yes.

Q. And the combined estimated rate of bowel perforation and serious infection, you were referring to synthetic midurethral slings?

A. Yes.

Q. Do you consider a serious infection rate of -- strike that.

When you wrote that "we estimate that bowel perforation and serious infections have a combined incidence of about 0.1 percent," did you attempt to ascertain what was the rate specific to serious infection?

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A. No. But we decide -- no. But I think that -- no, is the answer to your question.

Q. And when you say "serious infection," what do you mean by that?

A. Really, we were talking about life-threatening sepsis or infections that require -- retropubic infections that are either life threatening or require multiple operations to remove.

Some of them were, like, thigh infections -- just for example, thigh infections after transobturator slings were used that required three, four, five operations to deal with the infection and remove the mesh.

So these were the most serious infections, is what this was talking about.

Q. 0.1 percent, you would consider that rare?

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A. Yes.

Q. The thigh infection you mentioned with the transobturator slings, is it correct that the retropubic sling, like a TVT, has a lower risk of thigh infection than transobturators?

A. I would say it has no risk of thigh infection, or just about no risk.

But, also, there were serious kinds of infections. Again, life-threatening sepsis are the kinds of things we were talking about, not just -- yeah, that's what we were talking about.

Q. On the first page, top right, where it says, Furthermore, an analysis of 7,200 case logs submitted by American urologists for their certifying credentials in 2013, 83 percent of operations performed for incontinence in women were midurethral sling implantations.

Is that correct?

A. That's what it says, yes.

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except for a couple of patients that had multiple, multiple operations of synthetic slings in the same place.

And the reason is, to start with, the technique requires, without exaggeration, an extra maybe five minutes of dissection. And if you dissect into the retropubic space and put your finger in the retropubic space protecting the -- protecting the bladder and urethra, then you can pass the instrument from above instead of through the vagina and you're not doing it in a blinded fashion and you would completely protect the bladder and urethra. And in my estimation, you should almost never get into the bladder or urethra.

And, again, I've never done it, and it's never been -- except for these, I think, two instances.

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So that would eliminate a major cause, in my judgment, of subsequent erosion.

I cited a paper in there, again, by -- I think this was by Osborn, where there's a 26-fold increase, 26-fold increase in the likelihood of subsequent erosion into the vagina or the bladder in patients who have had a perforation of the bladder or urethra at the time of the original surgery.

And, again, in my opinion this is 100 percent, or practically 100 percent preventable. So that's the surgical technique, which is part of the -- you know, part of the procedure.

The second thing is, it makes little sense to me to use this, you know, bottoms-up approach. The bottoms-up approach

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that they use with the trocar passage precludes any protection of the bladder or urethra.

You just have to, for practical purposes, hope that you don't put the trocar into the bladder, the urethra or, even worse, the iliac artery of the obturator, all of which -- every one of those complications has occurred.

And, in my judgment, virtually never occurs, not once, if you use the top-down approach. I think it's not physically possible.

So that's the second point that I would change.

And the third point is that the trocar itself is too big, too thick and too pointed. You know, that trocar gets -- it's very easy to do significant damage to the adjacent structures if the trocar

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goes in the wrong place.

So if you use a much smaller trocar -- I mean, I alluded to the fact before that I use a Stamey needle, which is very thin and very unlikely to do any major damage. And if you pass it from above to below, the chances of injuring any adjacent organ is as close to zero as you can get.

That's it.

BY MR. SNELL:

Q. With regard to your statement that you would dissect more into the retropubic space --

A. Yes.

Q. -- what are the risks attendant with doing more dissection and deeper dissection into the retropubic space?

A. I don't think -- I don't think there's any. I mean, you're doing -- you're doing with your finger exactly the same thing that you're doing

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with a big blunt -- a big sharp instrument.

So whether you do it with your finger or an instrument, you are still going into the same place. I don't think there's any more hazard. I think there's less hazard.

That might not have been your question. Was the question the hazards or additional risks?

Q. Yeah, what's the -- are there additional risks by doing a larger dissection deeper into the retropubic space?

A. I think there are less risks.

Q. Does a larger incision have a higher risk of erosion?

A. Yes, it probably does. But this isn't a larger incision.

Q. Are you saying the TVT trocar is equivalent in size to your finger, and the incision -- strike that -- the dissection you would make up

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into the retropubic space?

A. Yeah, I don't -- we're talking about such a small incision that it's inconceivable to me that it would make much difference.

I would have to check my finger against the size of the trocar, but it's not very different. And my finger doesn't have a point at the end of it.

Q. Are there any clinical studies using midurethral slings that evaluate whether less dissection -- strike that.

Are there any clinical studies in midurethral slings that demonstrate that there is less risk when you do a larger dissection into the retropubic space?

A. I don't know.

Q. You mentioned the -- you would prefer to do a top-down approach as opposed to a bottom-up approach?

A. Well, yeah. Your specific

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question was, how do I think it could be improved. And I think that would be a great improvement.

Q. Do you know whether or not a top-down approach for TVT was ever offered or made available to surgeons?

A. I think -- no, I don't have an independent recollection.

Q. Do you know whether your opinion that proceeding from the top down as opposed to bottom up would lead to less risk of urethral perforation and other complications been has tested in any randomized control trials?

A. The technique that I'm talking about has not, to my knowledge, been done for this, so it hasn't been tested.

But it's been done thousands of times by me and other people that do autologous slings.

Q. Do you have that Ogah Cochrane review that we were looking at earlier that you cited in your review

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paper?

A. Yes.

MS. FITZPATRICK: Which one is this?

BY MR. SNELL:

Q. What exhibit is that, Doctor, the number?

A. Exhibit 5.

Q. You see this Ogah Cochrane review you cite to? I just want to show you where I'm at.

A. Yes.

Q. They did assess a bottom-to-top route compared with a top-to-bottom route, correct?

A. Yes.

Q. And they found the bottom-to-top route -- and that's the TVT retropubic route, correct?

A. Yes.

Q. -- was more effective than a top-to-bottom route, correct?

A. That's what it says.

But if you look at the -- I

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found studies that reported on a certain percent of women who had a bladder perforation with the TVT, what percent of those did not have long-term complications or sequelae from that perforation?

A. I am not aware of a single study that addresses that question in a meaningful way, let's put it that way, in a way that -- whose methodology would support those conclusions.

Q. For the synthetic midurethral slings, you all assessed the rate of pain was 1 percent, correct?

A. Based -- where are you now?

Q. In the same table we were looking at.

A. Yeah.

Q. Suggested complications, correct?

A. That was two studies, and there was -- I'm quite sure there was -- there was insufficient methodologies to come to those conclusions.

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We did not comment on the quality of the methodology, just the reports themselves.

Q. And then below that, there's sexual dysfunction.

And that rate was zero percent with the synthetic midurethral sling, correct?

A. Yeah. If you believe that one, I'll sell you a bridge. But, yes.

Q. And, actually, Doctor, on that point, if you look down below there, you all didn't denote with any type of symbol that that data were not reliable, did you?

A. No, I don't see that we did.

Q. In fact, in the legend, there is a symbol where you could have designated that, where it says, Although this estimate is based on published data, the panel believes the estimates are not consistent with their experience.

No one elected to put that symbol next to pain or sexual dysfunction

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for the midurethral sling, correct?

A. That is correct. But I think that at the very -- to be kind, it was an oversight.

There is no way that the group that I was involved with would say that the -- that there is zero and 1 percent chance of sexual dysfunction and/or pain after a midurethral sling.

That's inconsistent -- even though that's what the paper says, that is inconsistent with any data or anything I've ever been involved with, with this group.

Q. If you go back to the Burch -- so that's what you're saying now.

You've never published that, correct, that there is --

MS. FITZPATRICK: Objection.

BY MR. SNELL:

Q. Strike that.

You've never published that these data in the AUA guidelines are now

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unreliable, correct?

MS. FITZPATRICK: Objection. Misstates the testimony.

THE WITNESS: The panel -- the guideline document itself said that the quality of the studies was -- I forget the exact wording, either poor or -- said that the quality of the studies was not good, that it was -- and being part of the discussions, we lamented the fact that there were so few studies to make -- to come to any reasonable conclusions.

And we were forced, by the -- we were forced, by the dictates of the organizing body that put this together, they told us that we needed to rely on the data that was -- that the paper -- that -- the published data to come to our conclusions.

And that's what the group did. I don't think anybody -- I'm

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confident that nobody on that committee would say that there is a zero incidence of sexual dysfunction and a 1 percent incidence of pain after midurethral sling.

Every single study in the literature that I ever reviewed that looked at any -- either sexual -- either dyspareunia or pain has an incidence higher than 1 percent. So I don't know how this happened -- I don't know how this occurred.

BY MR. SNELL:

Q. Are you still a member of the AUA?

A. I am.

Q. Why?

A. Why am I a member?

Q. Why are you still a member of the AUA?

MS. FITZPATRICK: Objection.

THE WITNESS: Because I

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think it's an important organization and it provides valuable services to the public and its membership.

BY MR. SNELL:

Q. Well, if you look at the page before that, you'll see that you all did indicate -- what do you call that an ampersand?

MR. ROSENBLATT: Asterisk.

MR. SNELL: No, like a double S.

THE WITNESS: I know what you mean.

BY MR. SNELL:

Q. Do you see the page before that, Doctor, you all indicated, in two different places with that ampersand, that the data estimated were not consistent with their experience.

Do you see that? For bladder injury as well as vaginal erosion extrusion for synthetic slings at the bladder neck with bone anchors, correct?

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A. I see that.

Q. And if we turn back two pages, we were looking at the Burch colposuspension, the rate of pain you all reported in the stress incontinence guidelines for the Burch was 6 percent, correct?

A. Which page are you on?

Q. Back where we were, Burch colposuspensions, Table 16.

A. And where?

Q. It's at the bottom.

A. Okay.

Q. And the way these tables read is, there's different surgical methods that have their own column, correct?

A. Yes.

Q. And for the Burch colposuspension, you all reported that the rate of pain was 6 percent, correct?

A. Yes.

Q. And that was higher than what you reported for the midurethral

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sling, correct?

A. Yes.

Q. You reported that sexual dysfunction was 3 percent with the Burch colposuspension?

A. Yes.

Q. And that was less than what you reported for the midurethral sling, correct?

A. Yes.

Q. Do you believe these numbers for pain and sexual dysfunction with the Burch are now somehow inaccurate?

A. I don't know. I don't have an opinion about that. It's not something I reviewed.

Q. Where did you all -- I was trying to find it.

Where did you report, in these tables, ureteral injury?

A. I don't know if they're there.

Q. I see it. So ureteral injury, let's look right above where we